ATC coding

Anatomisch-Therapeutisch-Chemisches Klassifikationssystem

- Das **Anatomisch-therapeutisch-chemische Klassifikationssystem**, offiziell **Anatomical Therapeutic Chemical / Defined Daily Dose Classification** ist eine 1976 von der European Pharmaceutical Market Research Association (EPhMRA) entwickelte, 1990 dann vom *Collaborating Centre for Drug Statistics* der Weltgesundheitsorganisation adaptierte und offiziell herausgegebene internationale Klassifikation für Arzneistoffe.

- Die Klassifikation gilt für *Substanzen*, nicht für *Handelspräparate*. Aktuell ist die Version 13 (2003), in Deutschland eine gemäß dem Fünften Buch Sozialgesetzbuch (SGB V) adaptierte Version ATC/DDD – DIMDI (2004), die zusätzlich pflanzliche Substanzen enthält. Die meisten kommerziell vertriebenen Arzneimittel-Verzeichnisse und -Kataloge sind (neben der Pharmazentralnummer) auch nach dem ATC-Index der Einzelstoffe geordnet.

- Die Klassifikation enthält 5 Ebenen. Auf der ersten Ebene gibt es 14 Hauptgruppen, die sich nach dem Organ (zum Beispiel Herz) oder System (zum Beispiel Blutkreislauf) richten, auf die der Arzneistoff seine Hauptwirkung entfaltet. Die zweite und dritte Ebene sind Therapiegruppen beziehungsweise -untergruppen; die vierte und fünfte Ebene sind nach der chemischen Struktur geordnet.

ATC coding

Beispiel ➔ Acetylsalicylsäure (B01AC06)

Anwendung als Thrombozytenaggregationshemmer B01AC06

- Level 1: Buchstabe für die anatomische Gruppe. Davon gibt es 15 verschiedene (1 Buchstabe)
  B ➔ „Blut und blutbildende Organe“
- Level 2: Therapeutische Hauptgruppe (2 Ziffern)
  01 ➔ „Antithrombotische Arzneimittel“
- Level 3: Therapeutische/pharmakologische Untergruppe (1 Buchstabe)
  A ➔ „Antithrombotische Arzneimittel“
- Level 4: chemisch/therapeutisch/pharmakologische Untergruppe (1 Buchstabe)
  C ➔ „Thrombozytenaggregationshemmer, excl. Heparin“
- Level 5: Untergruppe der chemischen Substanz (2 Ziffern)
  06 ➔ Wirkstoff Acetylsalicylsäure

Anwendung als Schmerzmittel N02BA01

ATC coding
Beispiel mit Level 4 kodierten ATC Werten

Ingredient	CHLORHEXIDINE	
Selected ATC code	A01AB	
	ATC code	ATC text
ATC code 0	A01AB	ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT
ATC code 1	B05CA	ANTIINFECTIVES
ATC code 2	D08AC	BIGUANIDES AND AMIDINES
ATC code 3	D09AA	MEDICATED DRESSINGS WITH ANTIINFECTIVES
ATC code 4	G01AX	OTHER ANTIINFECTIVES AND ANTISEPTICS
ATC code 5	R02AA	ANTISEPTICS
ATC code 6	S01AX	OTHER ANTIINFECTIVES
ATC code 7	S02AA	ANTIINFECTIVES
ATC code 8	S03AA	ANTIINFECTIVES

ATC coding
Beispiel von http://www.whocc.no/atc/structure_and_principles/

- Prednisolone in single ingredient products is given several ATC codes due to different therapeutic use and different local application formulations

– A07EA01 Intestinal antiinflammatory agents	(enemas and foams)
– C05AA04 Antihemorrhoidals for topical use	(suppositories)
– D07AA03 Dermatological preparations	(creams, ointments and lotions)
– H02AB06 Corticosteroids for systemic use	(tablets, injections)
– R01AD02 Nasal decongestants	(nasal sprays/drops)
– S01BA04 Ophthalmologicals	(eye drops)
– S02BA03 Otologicals	(ear drops)

ATC coding – WHO Drug Dictionary
Beispiel von WHO DD

- Which levels of the ATC codes are used in WHO Drug Dictionary?

  – Since we have the Drug Record number to identify a generic product we do not use the 5th level of the ATC codes for this purpose. The Drug Record Number identifies the active ingredient in single substance product and the unique combination of substances in multi-substance products. This is a similar solution to the 5th level but it adds flexibility.

  – In the new structure preparations have been made for the 5th level of ATC codes because there are plans to introduce them in the future. To be able to introduce the 5th level codes we need an agreement with the WHO Collaborating Centre for Drug Statistics Methodology in Oslo.

CM domain

Auszug aus CM domain (firmenspezifisch)

Variable Name	Type	CDISC Notes (for domains) Description (for General Classes)	Core	Required/ Expected	CT	Format (length)	Example
CMTRT	Char	Verbatim medication name that is either pre-printed or collected on a CRF.	Req	Required	No	Char 200	PARACETAMOL (RATIOPHARM)
CMMODIFY	Char	If CMTRT is modified to facilitate coding, then CMMODIFY will contain the modified text.	Perm	Required	No	Char 200	PARACETAMOL
CMDECOD	Char	Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic medication name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external code list attributes. If an intervention term does not have a decode value in the dictionary then CMDECOD will be left blank.	Perm	Expected	No	Char 200	PARACETAMOL
CMINDC	Char	Denotes why a medication was taken or administered. Examples: NAUSEA, HYPERTENSION.	Perm	Required	GRT GRT00023 (CMINDC)	Char 200	POSTOPERATIVE PAIN
CMCLAS	Char	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable or omit CMCLAS.	Perm	Expected	ATC	Char 200	ANILIDES
CMCLASCD	Char	Class code corresponding to CMCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable or omit CMCLASCD.	Perm	Expected	ATC	Char 200	N02BE

Controlled Terminology für CMINDC

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	GRT Submission Value	GRT Synonym(s) (Questions)
GRT00023	GRT00023	Yes	CMINDC	CMINDC	Indication
G000040	GRT00023		CMINDC	ADVERSE EVENT <xx>	
G000041	GRT00023		CMINDC	POSTOPERATIVE PAIN	
G000042	GRT00023		CMINDC	RESCUE MEDICATION	
G000043	GRT00023		CMINDC	DIABETIC POLYNEUROPATHY	
G000044	GRT00023		CMINDC	OSTEOARTHRITIS	
G000045	GRT00023		CMINDC	PERIPHERAL NEUROPATHIC PAIN	

CM / SUPPCM Beispiel

Auszug aus CM domain

USUBJID	CMSEQ	CMSPID	CMTRT	CMMODIFY	CMDECOD	CMINDC	CMCLAS	CMCLASCD
TEST-AB-0001	1	3	FOLIC ACID	FOLIC ACID	FOLIC ACID	MEDICAL HISTORY RHEUMATIC ARTHRITIS		B03BB
TEST-AB-0001	2	4	MTX	MTX	METHOTREXATE	MEDICAL HISTORY RHEUMATIC ARTHRITIS		M01CX
TEST-AB-0001	3	1	METAMIZOL (NOVALGIN)	METAMIZOL (NOVALGIN)	METAMIZOLE SODIUM	MEDICAL HISTORY RHEUMATIC ARTHRITIS		N02BB

Auszug aus SUPPCM domain

USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
TEST-AB-0001	CMSEQ	1	ATCLEV2C	ATC Level 2 Code	B03	Assigned	
TEST-AB-0001	CMSEQ	1	ATCLEV2T	ATC Level 2 Decode	ANTIANEMIC PREPARATIONS	Assigned	
TEST-AB-0001	CMSEQ	1	ATCLEV3C	ATC Level 3 Code	B03B	Assigned	
TEST-AB-0001	CMSEQ	1	ATCLEV3T	ATC Level 3 Decode	VITAMIN B12 AND FOLIC ACID	Assigned	
TEST-AB-0001	CMSEQ	1	CMDICTVS	WHO DD Version	WHODD 01-SEP-2014	Assigned	
TEST-AB-0001	CMSEQ	1	DICTVS	MedDRA Version	18.0	Assigned	
TEST-AB-0001	CMSEQ	2	ATCLEV2C	ATC Level 2 Code	M01	Assigned	
TEST-AB-0001	CMSEQ	2	ATCLEV2T	ATC Level 2 Decode	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Assigned	
TEST-AB-0001	CMSEQ	2	ATCLEV3C	ATC Level 3 Code	M01C	Assigned	
TEST-AB-0001	CMSEQ	2	ATCLEV3T	ATC Level 3 Decode	SPECIFIC ANTIRHEUMATIC AGENTS	Assigned	
TEST-AB-0001	CMSEQ	2	CMDICTVS	WHO DD Version	WHODD 01-SEP-2014	Assigned	
TEST-AB-0001	CMSEQ	2	DICTVS	MedDRA Version	18.0	Assigned	
TEST-AB-0001	CMSEQ	3	ATCLEV2C	ATC Level 2 Code	N02	Assigned	
TEST-AB-0001	CMSEQ	3	ATCLEV2T	ATC Level 2 Decode	ANALGESICS	Assigned	
TEST-AB-0001	CMSEQ	3	ATCLEV3C	ATC Level 3 Code	N02B	Assigned	
TEST-AB-0001	CMSEQ	3	ATCLEV3T	ATC Level 3 Decode	OTHER ANALGESICS AND ANTIPYRETICS	Assigned	
TEST-AB-0001	CMSEQ	3	CMDICTVS	WHO DD Version	WHODD 01-SEP-2014	Assigned	
TEST-AB-0001	CMSEQ	3	DICTVS	MedDRA Version	18.0	Assigned	

CM / SUPPCM Vorschlag / Beispiel UMC Präsentation

CM and SUPPCM as SAS datasets

VIEWTABLE: Work.Cm

	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
1	YYY	CM	ZZZ	1	IBUPROHPEN	IBUPROFEN	IBUPROFEN	MULTIPLE	MULTIPLE
2	YYY	CM	ZZZ	2	DUOCET	DUOCET	PARACETAMOL W/TRAMADOL HYDROCHLORIDE	OTHER OPIOIDS	N02AX

VIEWTABLE: Work.Suppcm

	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	YYY	CM	ZZZ	CMSEQ	1	CMCDSYS	DRUG CODE CODING SYSTEM	WHODDEMAR2014B	DERIVED
2	YYY	CM	ZZZ	CMSEQ	1	CMCD	DRUG CODE	00109201001	DERIVED
3	YYY	CM	ZZZ	CMSEQ	1	CMCLASYS	MEDICATION CLASS CODING SYSTEM	ATC4	DERIVED
4	YYY	CM	ZZZ	CMSEQ	1	CMCLAS1	Medication Class 1	OTHER CARDIAC PREPARATIONS	DERIVED
5	YYY	CM	ZZZ	CMSEQ	1	CMCLAS2	Medication Class 2	ANTIINFLAMMATORY PRODUCS FOR VAGINAL ADMINISTRATION	DERIVED
6	YYY	CM	ZZZ	CMSEQ	1	CMCLAS3	Medication Class 3	PROPIONIC ACID DERIVATES	DERIVED
7	YYY	CM	ZZZ	CMSEQ	1	CMCLAS4	Medication Class 4	ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	DERIVED
8	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD1	Medication Class Code 1	C01EB	DERIVED
9	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD2	Medication Class Code 2	G02CC	DERIVED
10	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD3	Medication Class Code 3	M01AE	DERIVED
11	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD4	Medication Class Code 4	M02AA	DERIVED
12	YYY	CM	ZZZ	CMSEQ	2	CMCDSYS	DRUG CODE CODING SYSTEM	WHODDEMAR2014B	DERIVED
13	YYY	CM	ZZZ	CMSEQ	2	CMCD	DRUG CODE	01573601042	DERIVED
14	YYY	CM	ZZZ	CMSEQ	2	CMCLASYS	MEDICATION CLASS CODING SYSTEM	ATC4	DERIVED

Draft, beeing discussed.

the UPPSALA MONITORING CENTRE

WHO Drug Code

Drug Code

The term Drug Code refers to the unique numeric key in the B Format of the dictionary. The B format is the old format of the dictionary and it is a dictionary of Drug Names. A Drug Code identifies a name, either a trade name or a generic Preferred Name. The Drug Code is used also in the C Format, where it is not a unique key but still has the same meaning as in the B Format.

The Drug Code is aggregated from Drug Record Number (Drecno), Sequence number 1 and Sequence number 2. The code differs from the Medicinal Product ID in that it has a meaning. The code is not only a unique identifier of a name – it also gives information about the active ingredient(s) and salt/ester form of the substance.

A **Drecno** identifies a generic identification level. In most cases the generic identification level is the one active ingredient, but it can also identify a unique combination of active ingredients.

Sequence number 1 identifies the salt or the ester of the active ingredient in single ingredient Drecnos. The number '01' identifies the base substance, without any salt or ester, and values above '01' will identify salts and esters. Drecnos that identify more than one active ingredient will have only one Sequence 1 with value '01'.

Sequence number 2 identifies trade names and in some cases a synonym to a generic name, e.g. Acetaminophen as a synonym to Paracetamol. The entry with Sequence number 2 value '001' identifies the name of the generic Drecno level – the Preferred Name. In single ingredient Drecnos this will be the INN name, in multi ingredient Drecnos it will be the trade name of the first product with the given combination that was entered into the dictionary.

WHO Drug Code / ATC code
Beispiele

MP ID	Drecno	Seq 1	Seq 2	Name	Chemical compound
000011	123456	01	001	Ampicillin	Ampicillin
000015	123456	01	002	DrugnameAB	Ampicillin
000016	123456	01	003	DrugnameAC	Ampicillin
000013	123456	02	001	Ampicillin Sodium	Ampicillin Sodium
000017	123456	02	002	DrugnameAD	Ampicillin Sodium
000018	123456	02	003	DrugnameAE	Ampicillin Sodium

Type	Name	ATC code	Use	Form
Preferred Name	Atropine Sulfate	A03BA, S01FA		
Trade name	Atropine NM Pharma	A03BA	Antispasmodic	Injection substance
Trade name	Atropine Novartis	S01FA	Mydriatic and Cycloplegic	Eye drops

Substanzen in WHO Drug Dictionaries

- The primary name reference for non-proprietary names of substances is the International Non-proprietary Names (INN)

  International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.

- A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature (currently including those described from at least 1957 through the present), including organic and inorganic compounds, minerals, isotopes, alloys and nonstructurable materials (UVCBs, of unknown, variable composition, or biological origin).

Auszug aus Präsentation
„UMCs Support for CDISC Standards” 2014

- Referencing the correct dictionary – there are three versions of the WHODRUG, each released four times per year and should be standardized to remove ambiguity.
- Content of CMTRT, which may need to be split from a combined verbatim text and is hence modified.
- CMMODIFY seems to not be used extensively, although it seems it would serve a purpose.
- CMDECOD is often used by sponsors to hold the term that the reported name was coded to rather than the generic as the IG states.
- The inclusion of the drug code CMTRTCD provides a cross reference to any information that was not anticipated and makes the above fields less critical.
- What data is included in SUPPCM can be standardized for ease of use.
- Naming of dictionary related data in SUPPCM can be standardized for ease of use

ATC

- IG says to not include intermediate levels.
  - But sponsors have been asked to send all levels.
  - Great variability in which levels are submitted and how they are named

- Some drugs have multiple ATC codes
  - Most sponsors select a single code
  - Sponsors have been asked to send all codes regardless of which was chosen

- ATC term of levels 2-4 can repeat and need to be qualified by the code (”Enzymes” = A16AB, B01AD, B06AA, C04AF, D03B, M09AB)

- It has been suggested that level one (”Anatomical”) has most value.

- It has been suggested that an identifier of the dictionary/terminology is included with the data.

Suggestion for Data Sets

- Add CMTRTCD/”Drug Code” to main data set.
  - This is the link any additional information that may not be included in the dataset in case the need was not anticipated.
- Add CMTRTSYS/”Drug Coding System” to main data set (or standardize how to capture in define.xml).
  - To capture version and edition of the dictionary.
- Add CMCLASYS/”Medication Class Coding System” to main data set.
  - This opens up for future/other classifications than ATC.
- Capture ATC codes in SUPPCM according to well defined rules.

Suggestion for IG

- Describe clearly with examples how to use CMTRT, CMMODIFY, CMDECOD, CMTRTCD, CMTRTSYS, CMCLAS, CMCLASYS, CMCLASCD if WHO-DDE is used.
  - Leave some flexibility for sponsor/reviewer how to use CMCLASxxx, but describe how to use each of the ATC levels.

- Encourage the use of CMINDC

- Standardize QNAMs and QLABELs for ATC codes in SUPPCM.
  - Include both term and code when used.
  - Again, leave some flexibility for sponsor/reviewer how to use, but describe how to use each of the ATC levels.

6 Domain Models Based on the General Observation Classes

6.1 Interventions

Concomitant/Prior Medications (CM)

CM – Description/Overview for the Concomitant/Prior Medication Domain Model

Case report form (CRF) data that captures the concomitant and prior medications/therapies used by the subject. Examples are the concomitant medications/therapies given on an as needed basis and the usual background medications/therapies given for a condition.

CM – Specification for the Concomitant/Prior Medication Domain Model

cm.xpt, Concomitant Medications — Interventions, Version 3.2. One record per recorded intervention occurrence or constant-dosing interval per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
CMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CMGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
CMSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Examples: a number pre-printed on the CRF as an explicit line identifier or record identifier defined in the sponsor's operational database. Example: line number on a concomitant medication page.	Perm
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Topic	Verbatim medication name that is either pre-printed or collected on a CRF.	Req
CMMODIFY	Modified Reported Name	Char		Synonym Qualifier	If CMTRT is modified to facilitate coding, then CMMODIFY will contain the modified text.	Perm

Auszug aus SDTMIG 3.2
Concomitant/Prior Medications (CM)

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CMDECOD	Standardized Medication Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic medication name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes. If an intervention term does not have a decode value in the dictionary then CMDECOD will be left blank.	Perm
CMCAT	Category for Medication	Char	*	Grouping Qualifier	Used to define a category of medications/treatments. Examples: PRIOR, CONCOMITANT, ANTI-CANCER MEDICATION, or GENERAL CONMED.	Perm
CMSCAT	Subcategory for Medication	Char	*	Grouping Qualifier	A further categorization of medications/ treatment. Examples: CHEMOTHERAPY, HORMONAL THERAPY, ALTERNATIVE THERAPY.	Perm
CMPRESP	CM Pre-Specified	Char	(NY)	Variable Qualifier	Used to indicate whether (Y/null) information about the use of a specific medication was solicited on the CRF.	Perm
CMOCCUR	CM Occurrence	Char	(NY)	Record Qualifier	When the use of specific medications is solicited, CMOCCUR is used to indicate whether or not (Y/N) use of the medication occurred. Values are null for medications not specifically solicited.	Perm
CMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about a pre-specified medication was not answered. Should be null or have a value of NOT DONE.	Perm
CMREASND	Reason Medication Not Collected	Char		Record Qualifier	Describes the reason concomitant medication was not collected. Used in conjunction with CMSTAT when value is NOT DONE.	Perm
CMINDC	Indication	Char		Record Qualifier	Denotes why a medication was taken or administered. Examples: NAUSEA, HYPERTENSION.	Perm
CMCLAS	Medication Class	Char	*	Variable Qualifier	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow *Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable* or omit CMCLAS.	Perm
CMCLASCD	Medication Class Code	Char	*	Variable Qualifier	Class code corresponding to CMCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow *Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable* or omit CMCLASCD.	Perm
CMDOSE	Dose per Administration	Num		Record Qualifier	Amount of CMTRT taken. Not populated when CMDOSTXT is populated.	Perm
CMDOSTXT	Dose Description	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in CMDOSU. Example: 200-400, 15-20. Not populated when CMDOSE is populated.	Perm
CMDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for CMDOSE, CMDOSTOT, and CMDOSTXT. Examples: ng, mg, or mg/kg.	Perm
CMDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for CMTRT. Examples: TABLET, LOTION.	Perm
CMDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of CMDOSE within a specific time period. Examples: BID (twice daily), Q12H (every 12 hours).	Perm

Auszug aus SDTMIG 3.2
Concomitant/Prior Medications (CM)

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CMDOSTOT	Total Daily Dose	Num		Record Qualifier	Total daily dose of CMTRT using the units in CMDOSU. Used when dosing is collected as Total Daily Dose. Total dose over a period other than day could be recorded in a separate Supplemental Qualifier variable.	Perm
CMDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.	Perm
CMROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for CMTRT. Examples: ORAL, INTRAVENOUS.	Perm
CMSTDTC	Start Date/Time of Medication	Char	ISO 8601	Timing		Perm
CMENDTC	End Date/Time of Medication	Char	ISO 8601	Timing		Perm
CMSTDY	Study Day of Start of Medication	Num		Timing	Study day of start of medication relative to the sponsor-defined RFSTDTC.	Perm
CMENDY	Study Day of End of Medication	Num		Timing	Study day of end of medication relative to the sponsor-defined RFSTDTC.	Perm
CMDUR	Duration of Medication	Char	ISO 8601	Timing	Collected duration for a treatment episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm
CMSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the medication relative to sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", ONGOING or "CONTINUING" was collected, this information may be translated into CMSTRF.	Perm
CMENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the medication relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING, or "CONTINUING" was collected, this information may be translated into CMENRF.	Perm
CMSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the medication as being before or after the reference time point defined by variable CMSTTPT.	Perm
CMSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by CMSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
CMENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the medication as being before or after the reference time point defined by variable CMENTPT.	Perm
CMENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by CMENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

Auszug aus SDTMIG 3.2
Concomitant/Prior Medications (CM)

CM – Assumptions for the Concomitant/Prior Medication Domain Model

1. CM Definition and Structure
   a. CRF data that captures the Concomitant and Prior Medications/Therapies used by the subject. Examples are the Concomitant Medications/Therapies given on an as-needed basis and the usual and background medications/therapies given for a condition.
   b. The structure of the CM domain is one record per medication intervention episode, constant-dosing interval, or pre-specified medication assessment per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis. The submission dataset structure may differ from the structure used for collection. One common approach is to submit a new record when there is a change in the dosing regimen. Another approach is to collapse all records for a medication to a summary level with either a dose range or the highest dose level. Other approaches may also be reasonable as long as they meet the sponsor's evaluation requirements.
2. Concomitant Medications Description and Coding
   a. CMTRT captures the name of the Concomitant Medications/Therapy and it is the topic variable. It is a required variable and must have a value. CMTRT should only include the medication/therapy name and should not include dosage, formulation, or other qualifying information. For example, "ASPIRIN 100MG TABLET" is not a valid value for CMTRT. This example should be expressed as CMTRT= "ASPIRIN", CMDOSE= "100", CMDOSU= "MG", and CMDOSFRM= "TABLET".
   b. CMMODIFY should be included if the sponsor's procedure permits modification of a verbatim term for coding.
   c. CMDECOD is the standardized medication/therapy term derived by the sponsor from the coding dictionary. It is expected that the reported term (CMTRT) or the modified term (CMMODIFY) will be coded using a standard dictionary. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.
3. Pre-specified Terms; Presence or Absence of Concomitant Medications
   a. Information on concomitant medications is generally collected in two different ways, either by recording free text or using a pre-specified list of terms. Since the solicitation of information on specific concomitant medications may affect the frequency at which they are reported, the fact that a specific medication was solicited may be of interest to reviewers. CMPRESP and CMOCCUR are used together to indicate whether the intervention in CMTRT was pre-specified and whether it occurred, respectively.
   b. CMOCCUR is used to indicate whether a pre-specified medication was used. A value of Y indicates that the medication was used and N indicates that it was not
   c. If a medication was not pre-specified the value of CMOCCUR should be null. CMPRESP and CMOCCUR is a permissible fields and may be omitted from the dataset if all medications were collected as free text. Values of CMOCCUR may also be null for pre-specified medications if no Y/N response was collected; in this case, CMSTAT = NOT DONE, and CMREASND could be used to describe the reason the answer was missing.
4. Additional Timing Variables
   a. CMSTRTPT, CMSTTPT, CMENRTPT and CMENTPT may be populated as necessary to indicate when a medication was used relative to specified time points. For example, assume a subject uses birth control medication. The subject has used the same medication for many years and continues to do so. The date the subject began using the medication (or at least a partial date) would be stored in CMSTDTC. CMENDTC is null since the end date is unknown (it hasn't happened yet). This fact can be recorded by setting CMENTPT="2007-04-30" (the date the assessment was made) and CMENRTPT="ONGOING".
5. Additional Permissible Interventions Qualifiers
   a. Any additional Qualifiers from the Interventions Class may be added to this domain.